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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI,
STEWART & OLSTEIN
6 BECKER FARM ROAD
ROSELAND, NJ 07068

EXAMINER
WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
1623	12

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,121	COSTIN, JAMES C.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2003 has been entered.

2. The amendment filed August 28, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) New Claims 7-12 have been added.
(B) Comments regarding Office Action have been provided drawn to:
    (i) 102(e) rejection, which has been maintained for the reasons of record;

3. Claims 4-12 are pending in the case.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

5. Claims 4-6 stand rejected under 35 U.S.C. 102(e) as being anticipated by Pfirrmann (US Patent No. 6,011,030) for the reasons already of record on pages 2 and 3 of the Office Action mailed August 20, 2002.

6. Applicant's arguments filed August 28, 2003 have been fully considered but they are not persuasive. Applicants argue against the Examiner's position wherein the Examiner relies upon MPEP § 2112.02, which recites that when a claim recites using an old composition or structure (Taurolidine) directed to a result or property of that composition or structure, then the claim is anticipated. Applicants argue that it is not the property or a result that is instantly claimed, it is the use in humans and warm-blooded animals of Taurolidine to prevent the molecular biological transfer of genes between

differing strains of bacteria based upon the now better appreciated chemical behavior of Taurolidine at the cellular level. This argument is not persuasive since the bacteria in the instantly claimed method are already known in the art as being susceptible to Taurolidine. For example, see instant Claim 6 wherein the bacterial is recited as Staphylococcus aureus which can be compared to passages disclosed in the Pfirrmann patent at column 3, lines 25 to 34, wherein Staphylococcus aureus (recited at line 26) is set forth as a bacteria that can be treated in a patient by administering Taurolidine (recited at line 30).

Applicants further argue against the rejection on the ground that the Pfirrmann patent is silent on the independent claimed elements, which set forth a human or other warm-blooded animal harboring of bacteria comprising plasmid materials containing genes capable of resisting the antibiotic vancomycin from a vancomycin resistant strain of bacteria. This argument is not persuasive since the Pfirrmann patent set forth a method of treating a patient with microbial infections, such as bacterial and/or fungal infection, wherein vancomycin resistant Enterococcus faecalis is specifically recited. The vancomycin resistant Enterococcus faecal is encompass by the phrase "vancomycin reistant strain of bacteria" which is set forth in the instant claims. "Plasmid materials containing genes" is an inherented property of the vancomycin resistant bacteria of the Pfirrmann patent. Accordingly, the rejection of Claims 4-6 under 35 U.S.C. 102(e) as being anticipated by Pfirrmann (US Patent No. 6,011,030) is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

7. Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfirrmann (US Patent No. 6,011,030) in view of Pfirrmann (US Patent No. 5,972,933).

Applicant claims a method for the prevention of the transfer of plasmid materials containing genes capable of resisting the antibiotic vancomycin from a vancomycin resistant strain of bacterial to another, different strain of bacteria comprising administering to a human or other warm blooded animal harboring bacteria containing said plasmid materials an effective amount of the compound 4,4'-methylenebis

(tetrahydro-1,2,4-thiadiazine 1,1-dioxide). Additional limitations in the dependent claims include the different strain of bacteria being Staphylococcus aureus; said 4,4'-methylenebis(tetrahydro-1,2,4-thiadiazine 1,1-dioxide) is combined with at least one additional antibiotic; the additional antibiotic being selected from gentamicin, methicillin, and vancomycin; said staphylococcus aureus bacteria being vancomycin-intermediate susceptible; said compound being administered orally; said compound being combined with a pharmaceutical carrier; said compound being in tablet form; and said tablet containing 500 mg of said 4,4'-methylenebis(tetrahydro-1,2,4-thiadiazine 1,1-dioxide).

The Pfirrmann '030 patent discloses a method of treating a patient with bacterial infection so as to prevent release of bacteria endotoxins, comprising administering to said patient an antimicrobial amount of an antimicrobial compound which may be selected as Taurolidine which is exotoxin-inactivating, without administration of an antibiotic to said patient and prior to substantial administration of any antibiotic to said patient, so as to substantially inactivate said bacteria without releasing said endotoxin and substantially reduce said symptoms (see column 2, 6th paragraph of the Pfirrmann '030 patent). Taurolidine is the common name for 4,4'-methylenebis(tetrahydro-1,2,4-thiadiazine 1,1-dioxide). The bacterial toxins that are referred to in the Pfirrmann '030 patent comprise the plasmid materials set forth in instant Claim 1. See column 3, 4th paragraph of the Pfirrmann '030 patent where a list of bacterial and/or fungal infection is disclosed, which include methicillin-resistant staphylococcus aureus and vancomycin-resistant Enterococcus faecalis, which embraces the passage disclosed in instant Claims 4 and 5 whereby plasmid materials are prevented from transferring from a vancomycin resistant strain of bacteria to another, different strain of bacteria. Pfirrmann '030 discloses that Taurolidine is administered for approximately 3-5 days without antibiotic administration, after which antibiotics or combinations of antibiotics can be administered to the patient with or without further Taurolidine administration, which embraces the subject matter of instant Claim 6. The instant claims differ from the Pfirrman '030 patent by claiming that the Taurolidine is administered orally and in form of tablet that contains 500 mg of Taurolidine.

The Pfirrmann '933 patent discloses the application of a method of treating microbial digestive tract infection of a patient, comprising introducing into the digestive tract of the patient a non-antibiotic, antimicrobial medicament effective against antibiotic-resistant microbes. Pfirrmann '933 describes that the method as being advantageous for use against infections of the gut by antibiotic-resistant microorganism such as antibiotic resistant strains of gram negative or gram positive bacteria, antibiotic-resistant and multi-resistant strains of Enterococci, antibiotic-resistant and multi-resistant strains of Staphylococci, Enterococcus faealis, Enterococcus facium, Staphyococcus aureus, vancomycin-resistant Enterococcus faecalis (VRE) stains, and methicillin resistant Staphylococcus aureus (MRSA) strains (see column 2, lines 33-48). See column 2, line 6, wherein the antimicrobial compound may be selected as Taurolidine, wherein Taurolidine is the common name for the compound 4,4'-methylenebis (tetrahydro-1,2,4-thiadiazine 1,1-dioxide). Also, see column 4, lines 36-42, wherein the Pfirrmann '933 patent teaches the addition of Taurolidine to antibiotic-treated cultures which prevents a rise in TNF production as a result of nearly complete neutralization of release endotoxins, which embraces the subject matter of instant Claim 6 wherein the Taurolidine is combined with an additional antibiotic or antibiotics. Furthermore, see column 2, 8th paragraph wherein the antimicrobial medicament may be administered orally. See Example 2, wherein 500 mg of Taurolidine may be a component in a tablet along with other ingredients, which encompasses the subject matter of instant Claims 10-12.

One of ordinary skill in this art would be motivated to combine the teachings of the Pfirrmann '030 patent with the teachings of the Pfirrmann '933 patent for a rejection of the claims under 35 U.S.C. 103 since both references describe the administration of Taurolidine for the treatment of antibiotic-resistant bacteria. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the Taurolidine which is administered to a patient, infected with antibiotic-resistant bacteria, as disclosed in the Pfirrmann '030 patent in tablet form comprising 500 mg of Taurolidine in view of the recognition in the art, as evidenced by Pfirrmann '933 patent, that Taurolidine as a component of a tablet along with other ingredients that include a

pharmaceutical carrier is effective for treating a patient infected with antibiotic-resistant bacteria.

8. Applicant's arguments with respect to Claims 4-12 have been considered but are moot in view of the new ground(s) of rejection.

Summary

9. All the pending claims are rejected.

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

12. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
E.White

James O. Wilson
Supervisory Primary Examiner
Technology Center 1600